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IDEAS AND TECHNICAL INNOVATIONS

Long-term actuarial survivorship analysis of an interspinous stabilization system

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Abstract In 1986, an interspinous dynamic stabilization system (the prototype of the current Wallis implant) was designed to stiffen unstable operated degenerate lumbar segments with a hard interspinous blocker to limit extension and a tension band around the spinous processes to secure the implant and limit flexion. Restoring physiological mechanical conditions to the treated level(s) while preserving some intervertebral mobility was intended to treat low-back pain related to degenerative instability without increasing stress forces in the adjacent segments. The procedure was easily reversible. If low back pain persisted or recurred, the device was removed and stability was achieved using fusion. The intermediate-term results were promising, but the long-term safety and efficacy of this dynamic interspinous stabilization device has not been previously documented. We retrospectively reviewed the hospital files of all the patients ($n = 241$) who had this dynamic stabilization system implanted between 1987 and 1995, contacting as many as possible to determine the actuarial survivorship of the system. In this manner, 142 of the 241 patients (58.9%) were contacted by telephone. The endpoints used for the survivorship analysis were 'any subsequent lumbar operation' and 'implant removal'. At 14 years follow-up, values of actuarial survivorship with 95% confidence interval were 75.9 ± 8.3 and 81.3 ± 6.8% for the endpoints 'any subsequent lumbar operation' and 'implant removal', respectively. There was no difference in survivorship of multiple-level implants with respect to single-level devices. Although the conclusions of the present study must be tempered by the 41% attrition rate, these findings support the long-term safety of this system, and possibly long-term protective action against adjacent-level degeneration by motion preservation. Outcomes at least equivalent to those of fusion were observed without the primary drawbacks of fusion.

Keywords Dynamic stabilization · Actuarial survivorship · Lumbar · Degenerate spondylosis · Motion preservation

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Introduction

Lumbar degenerative disease is mediated essentially by biomechanical, environmental and genetic factors [3, 18, 19, 21]. In many subjects, intersegmental degeneration may proceed with no accompanying clinical symptoms, even when severe changes are present on imaging studies. In others, however, degenerative changes are accompanied by symptoms of instability, notably low back pain. In 1986,

we developed a lumbar implant designed to stiffen unstable operated degenerative segments without entirely eliminating mobility. Initially called the Mechanical Normalization System, the device will be designated the 'first-generation Wallis' implant below, in reference to the name given the current, updated version of the implant. It was based on an extra-articular concept, which made the procedure reversible. The structural spinal elements except for the interspinous ligament were left intact. This made it possible, in case of recurrent or persistent low back pain, to remove the system and perform fusion, the only widespread surgical alternative in 1986. The primary hypotheses of this posterior stabilization system were twofold. The first hypothesis was that by artificially restoring more physiological mechanical conditions in the treated degenerate intervertebral segment, we might not only relieve or prevent instability-related low-back pain, but also alter the rate of disc destruction at that level. The second hypothesis was that if this interspinous stabilization system preserved more mobility in the treated segments than fusion would, then the degenerative process in the adjacent intervertebral levels might progress more slowly [6, 7]. The short- and intermediate-term clinical efficacy was promising [17]. The purpose of the present retrospective study was to evaluate the safety and efficacy of this implant by actuarial survivorship analysis using 'any subsequent lumbar operation' and 'removal of the device' as endpoints.

Materials and methods

Patients

Between 1987 and 1995, we applied single- or multiple-level interspinous stabilization devices to patients with symptomatic degenerative instability during the course of a lumbar procedure. During this period, a total of 241 patients received this device. The devices were implemented to increase lumbar intersegmental stability after decompressive procedures for isolated canal stenosis, recurrent disc herniation, massive primary disc herniation, or canal stenosis decompensated by primary or recurrent herniated disc. Because seating of these implants in the L5–S1 interspinous space required a prominent S1 spinous process, they could not be routinely used at that level. Even though the system was conceived for patients with low back pain related to early degenerative intersegmental lesions, all of the patients had degenerative changes for which fusion had been scheduled. This was done for ethical reasons in view of the novelty of both the device and the concept, but it also permitted to test the concept and safety of dynamic stabilization by interspinous blockers and posterior tension bands in patients with late degenerative changes. In this group of patients who would otherwise have undergone a fusion procedure, the goal was to delay fusion for as long as possible with a simple, relatively superficial device that preserved the segmental anatomy. Chronic low back pain resistant to conservative care was present in most of the patients scheduled for fusion. In some cases of recurrent disc or canal stenosis, fusion had been scheduled to prevent potential postoperative low back pain, the incidence of which was high in these subgroups. Patients were given a choice between fusion and the first-generation dynamic stabilization device.

In 2004, the initial patient files of these patients were requested for analysis to determine general preoperative demographic values, preoperative symptoms and signs, the surgical indications, peroperative data, short- and intermediate-term follow-up status, and most recent contact information. We mandated a physician to use the contact information from the hospital files to find as many of the living patients as possible (or the immediate family of deceased patients) for a telephone interview to ascertain essentially whether the implant was still in place, and the date and nature of subsequent lumbar operations, when applicable. Many of the 241 patients moved during the 10–15 years after the operation and could not be located or could not be contacted by telephone. A private investigator was hired to locate the patients who could not be found in the phonebook or by Internet in order to reduce the attrition rate as much as possible. French law allows patients to take their files out of the hospital. Among the 142 patients contacted, the files of ten were missing from the hospital or were incomplete. In these patients, the information on the level operated was obtained by telephone, but we judged this information to be unreliable. If the patient had died, the family was questioned to determine the date of death and whether the implant was still in place at the time of death. In our opinion, people reliably know if their spouse has undergone a second lumbar operation, in general. Each specific account by a spouse, when necessary, was obtained with as little prompting as possible. If the information was judged to be unreliable, that patient was excluded from the analysis. Data was obtained in this manner for nine patients. In almost all of the patients, the information obtained from these telephone interviews was cross-checked with the available data gathered from the hospital files of these patients.

Implants

The implant (Fig. 1) included a double braided woven polyester (Dacron) cord fixed to a titanium spacer and, when more than one intervertebral segment was treated, additional interspinous spacers made of polyacetal (Hostaform) were used. This created a semiconstrained system

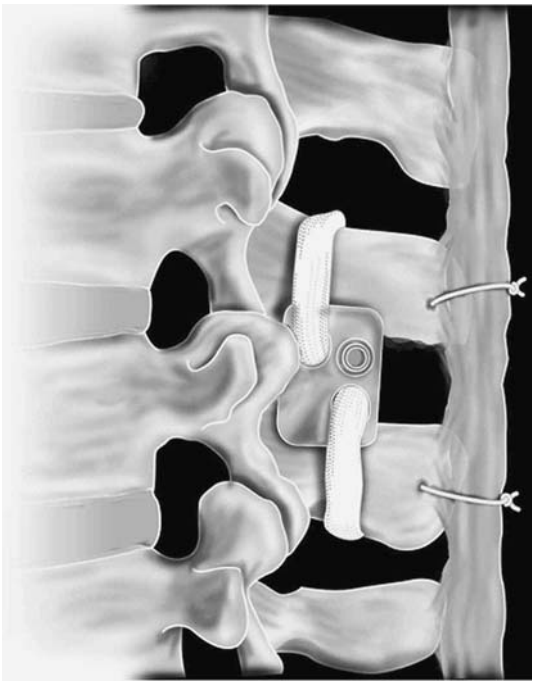

Fig. 1 The first-generation dynamic stabilization implant

designed to stabilize the intervertebral axis of extension and flexion and reduce the mobility of the instrumented segment. The spacers placed between the posterior arches were intended to produce an unloading effect, reducing pressure in the facet joints and posterior portion of the intervertebral endplates in lordosis. There was a radiodense marker inside the cord throughout its length. The polyacetal spacers were radiolucent.

Surgical technique

After the supraspinous ligament was detached, the interspinous space was trimmed with a gouge and a high-speed drill to create a trapezoid opening so as to prevent the posterior displacement of the spacer. When instrumenting the L5–S1 space, if the first sacral spinous process was atrophic, a groove for the cord was cut in the lamina with a high-speed drill, or the sacral crest was perforated transversely to thread the cord through it. The spacers were chosen to fit the trimmed interspinous space and avoid kyphosis of the instrumented segment. The lordosis of the lumbar column was verified using an image intensifier before final fixation of the implant.

The first spacer (the only spacer if a single level was instrumented) was made of titanium, delivered attached to a lone woven polyester cord. The surgeon threaded the cord around the spinous processes and through the spacers in Fig. 8 fashion. When tension had been applied throughout all levels, we blocked the extremity of the cord by firmly lodging a taper beside it in the metal spacer. The supraspinous ligament was reattached to each spinous process using separate transfixing sutures.

Postoperative care

Patients were encouraged to begin walking the first day after the intervention, and wore a lumbar orthosis for 45 days. Isometric exercises were prescribed to maintain the muscle tone of the trunk. After discontinuation of the lumbar orthosis, rehabilitation was pursued with emphasis on tightening the lower back muscles. Patients were generally seen between 1 and 2 months after the operation, then again after 6 months if they lived within a 50-mile radius of our spinal unit. At discharge from the unit and at follow-up visits, we urged them and their general practitioner to consult us if any low-back or leg problem persisted or subsequently developed.

Outcome measures

The information gathered was applied to establish actuarial survival curves using Statview software (SAS Institute, Cary, NC, USA).

Results

Telephone interviews were obtained for 142 patients. There was no significant difference between the 142 patients we were able to contact for the telephone interview and the overall group of 241 patients in age, gender, indication, levels operated, or number of levels operated. In other words, no selection bias was introduced in contacting only the patients who were contactable [4]. The initial files of 132 of the 142 patients (93%) were available for study. The age of the patients at the time of operation was 46.9 ± 12.0 years. There were 105 men (73.9%) and 37 women (26.1%). The operated intervertebral levels could be determined from either the initial hospital file or long-term follow-up films in 136 (95.8%) of the subjects. Tables 1, 2 and 3 show the indications, levels operated, and number of levels involved in these patients.

Thirty of these patients (21.1%) underwent subsequent lumbar surgery. Information on these patients is shown in Table 4. Figure 2 shows the years of follow-up of all 142 patients contacted by telephone, whether or not they had undergone subsequent lumbar surgery.

At long-term follow-up, nine (24.3%) of the 37 women contacted no longer had the implant. Among the 105 men contacted, 17 (16.2%) no longer had the implant. This tendency was not significant (Fisher exact test $P = 0.32$). The average age at operation of the patients who still had

Table 1 Indications for 133 of the 142 patients operated between 1987 and 1995

Indications	Isolated canal stenosis	Primary herniated disc	CS + HD	Recurrent herniated disc	CS + RHD	Other
Number of patients	58 (43.6%)	15 (11.3%)	25 (18.8%)	27 (20.3%)	3 (2.3%)	5 (3.8%)

CS Canal stenosis, *HD* herniated disc, *RHD* recurrent herniated disc

Table 2 Distribution of single-level and multiple-level implants (136 of 142 patients)

Number of levels instrumented	One	Two	Three	Four
Number of patients	86 (64.0%)	24 (17.6%)	19 (14.0%)	6 (4.4%)

the implant at follow-up was 47.9 ± 12.3 years and that of the patients who no longer had the implant was 42.7 ± 10.1 years. This difference was not significant ($P > 0.6$).

Concerning the 142 patients contacted by telephone, actuarial survivorship analysis was performed considering any subsequent lumbar or lumbosacral operation as endpoint (Fig. 3). This corresponds to the 30 patients who were either reoperated at the treated level or who subsequently had a lumbar procedure involving other levels. In 26 of these 30 patients, the treated level was reoperated and the implant was removed. The actuarial survivorship curve considering removal of the device as endpoint is shown in Fig. 4. Among the patients contacted by telephone, 36% were treated at more than one lumbar segment. Figure 5 shows the survivorship curves of one-level implants (endpoint implant removal) compared to the survivorship of multiple-level implants. There was no significant difference in these two curves. The patients could also be roughly divided into two groups, according to whether or not a disc herniation had been resected during the index operation. Figure 6 compares the actuarial survival curve for the 72 long-term follow-up patients who initially underwent discectomy with or without bony decompression with that of the 57 patients who initially underwent bony decompression for canal stenosis without concomitant discectomy. There was no significant difference in these two curves.

Discussion

The greatest limitation of the present retrospective (a limitation in itself) study was the high attrition rate. Of the 241 patients who received a first-generation Wallis device between 1987 and 1995, we were unable to contact 99 (41%) for various reasons, of which the most frequent was change of address. A private investigator sought the addresses of these patients for several months without success; a number of these patients had probably left the region. Although similar attrition rates have been reported in the recent spinal literature for retrospective study with comparable follow-up [7, 8], this shortcoming of the present study must be kept in mind when considering the results. Survivorship analysis is useful when a large percentage of patients have been lost to follow-up, provided that the characteristics of patients for whom the data are incomplete are similar to those of patients for whom the data are complete [4]. This was the case in the present study in terms of age, gender, indication, levels operated, and number of levels operated.

The retrospective finding that the actuarial survivorship of the system was 82.8 ± 6.3% at 10 years in terms of overall reoperation rate (Fig. 3) provides support to the clinical impression we had acquired that interspinous stabilization of degenerative lumbar segments is not only effective, but is also safe over the long term. Probably contributing to the observed reoperation rate was the low number of implant-related complications (two spinous process fractures and one possible lamina fracture), perhaps due to the extraarticular nature of the procedure, which causes no damage to the disc or the facet joint capsules. Another reason for the reduced complication rate may have been the fact that the implant linked the vertebrae without screws or other means of transfixing the cortical bone. Pedicle screw placement is a well-documented source of complications in posterior fusion proce-

Table 3 Segments treated with single- or multiple-level implants among 216 segments in 136 (out of 142) patients operated between 1987 and 1995

Segments instrumented	L1–L2	L2–L3	L3–L4	L4–L5	L5–S1
Number of segments	3 (1.4%)	20 (9.3%)	50 (23.1%)	121 (56.0%)	22 (10.2%)

Table 4 Information concerning the 30 patients (among the 142 patients contacted by telephone for long-term follow-up) who underwent further lumbar surgery

Age at op	Sex	Indication	Nb of levels	Implant levels	Years in place	Reason for revision	Adjacent level involved	Implant removed	Revision procedure	Years follow-up
38	F	CS (+DH)	3	L2–5	0.4	Persistent low back pain	No	Yes	Fusion (extended several months later)	9.7
47	M	CS	3	L3–S1	0.6	U	U	Yes	Fusion	15.4
39	M	CS	1	L4–5	0.6	Persistent low back pain	No	Yes	Fusion	14.5
29	M	RDH	1	L4–5	0.7	U	Yes	No	Fusion (L5–S1)	10.1
74	M	CS (+DH)	2	L3–5	0.8	Spinous process fracture	No	Yes	Fusion	14.5
36	M	RDH	1	L4–5	1.0	Persistent low back pain (loosening of taper placed on wrong side)	No	Yes	Fusion (L4–L5)	9.4
33	M	U	U	U	1.1	Recurrent herniated disc	U	Yes	Fusion (L4–S1)	16.3
34	F	DH	1	L4–5	1.1	Persistent low back pain	Yes	Yes	Fusion (L4–S1)	10.5
51	M	CS (+DH)	1	L4–5	1.2	Persistent low back pain	U	Yes	U	16.1
57	M	CS	1	L5–S1	1.7	Persistent low back pain	No	Yes	Fusion (after canal enlargement)	16.0
33	F	RDH	1	L5–S1	1.8	Recurrent herniated disc	No	Yes	Fusion (L5–S1)	11.3
48	M	CS (+DH)	2	L3–5	2.1	Spinous process fracture	No	Yes	Fusion (posterolateral)	16.2
42	F	DH	1	L4–5	2.1	Recurrent herniated disc	No	No	Discectomy	12.8
35	M	RDH	1	L4–5	2.2	Recurrent herniated disc	Yes	Yes	Fusion (L4–S1 after discectomy and canal enlargement)	11.6
57	M	CS (+DH)	3	L3–S1	2.4	Recurrent herniated disc	No	Yes	Fusion (L3–S1 after discectomy and laminectomy)	15.8
34	M	RDH	1	L4–5	3.0	Recurrent herniated disc	No	Yes	Fusion (L4–L5 after discectomy)	9.0
40	F	RDH	1	L4–5	3.1	L5–S1 herniated disc	Yes	No	Discectomy	13.8
30	M	RDH	1	L4–5	3.2	Recurrent herniated disc	No	Yes	Fusion (L4–L5 after canal enlargement)	9.0
37	M	U	U	U	3.8	Recurrent herniated disc	No	Yes	Fusion (L4–L5)	12.0
40	F	CS	1	L4–5	4.5	Canal stenosis	Yes	Yes	Laminectomy (L2–L5)	10.2
32	M	DH	1	L4–5	4.9	Fall from a ladder with loosening of Morse taper	Yes	Yes	Fusion (two levels)	13.8
37	F	CS	1	L4–5	5.1	Low back pain	Yes	Yes	Fusion (L4–S1)	12.3
40	F	CS	1	L4–5	6.1	Recurrent herniated disc	Yes	Yes	Fusion (L3–L5 extended to S1 one year later)	13.7
62	M	CS	1	L4–5	6.2	Low back pain and sciatica	Yes	No	Unilateral L5–S1 foraminal decompression	10.2
42	M	CS (+DH)	1	L4–5	6.4	Recurrent herniated disc	No	Yes	Removal implant and discectomy (fusion three years later)	10.5
51	F	CS	2	L3–5	6.9	U	Yes	Yes	Fusion (L3–S1 extended to T10 two years later)	10.0
52	F	CS	2	L3–5	8.7	Low back pain	U	Yes	Fusion	15.0
44	M	CS	1	L4–5	9.1	Low back pain: possible left L5 lamina fracture	Yes	Yes	Fusion (posterolateral L3–S1)	11.8
42	M	CS (+DH)	2	L3–5	12.0	U	Yes	Yes	Fusion (L3–S1)	17.2
48	F	CS	4	L2–S1	15.1	Spondylolisthesis L3–L4 with left leg pain	No	Yes	Fusion (L3–L4)	15.1

U Undetermined

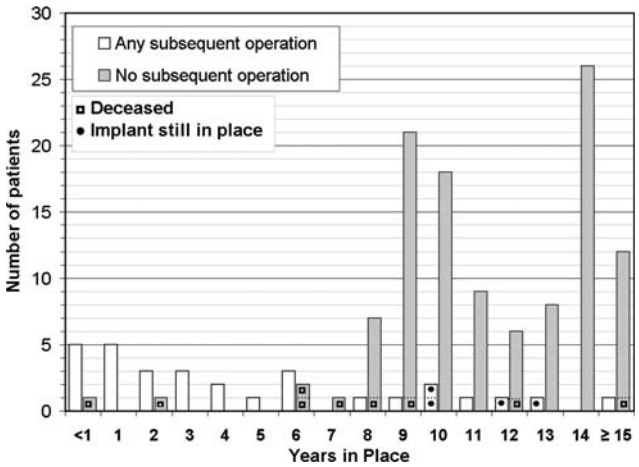

Fig. 2 Histograms showing the distribution of patient follow-up in years

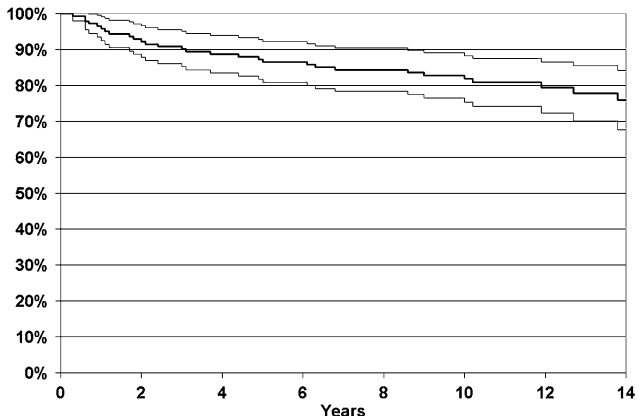

Fig. 3 For the 142 patients contacted by telephone, actuarial survivorship (±95% CI) considering any subsequent lumbar or lumbosacral operation as endpoint; 10 year 82.8 ± 6.3%; 14 year 75.9 ± 8.3%

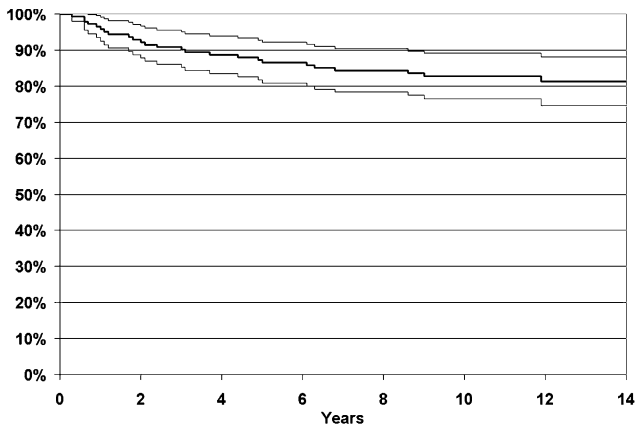

Fig. 4 Actuarial survivorship curve considering removal of the device as endpoint (±95% CI); 10 year 82.8 ± 6.3%; 14 year 81.3 ± 6.8 %

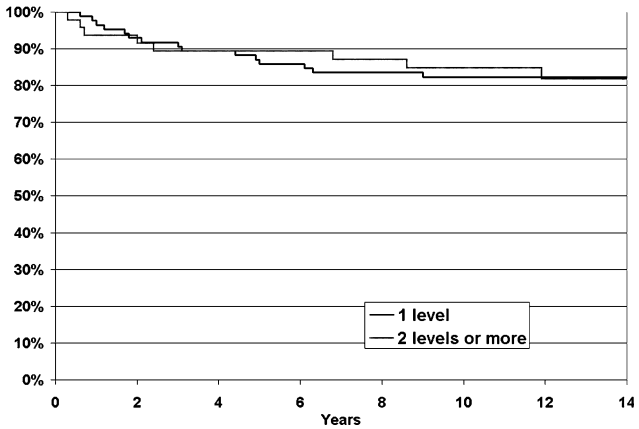

Fig. 5 Actuarial survivorship curves of one-level implants compared with multiple-level implants considering removal of the device as endpoint. No significant difference

dures [9, 12]. Early loosening attributed to toggle-related osteolysis around screws has been reported in pedicle screw-based dynamic stabilization systems [13].

Regarding adjacent segment degeneration, our results compare favorably with the findings of Ghiselli et al. [6]. The latter authors studied a group of 215 patients who had undergone single-level or multiple-level fusion for degenerative lumbar conditions. Only patients who had successful fusion were included. Their Kaplan Meier survivorship analysis predicted that 36.1% of patients would have revision surgery at a segment adjacent to fusion 10 years after the index operation. In their subgroup of 50 patients with the longest follow-up (average 13 years), 30 (60%) had

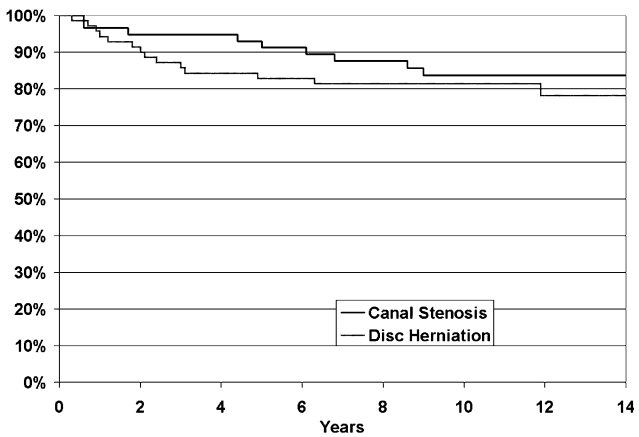

Fig. 6 Actuarial survivorship considering implant removal as endpoint for the 72 long-term follow-up patients who initially underwent discectomy with or without bony decompression compared to the 57 patients who initially underwent bony decompression for canal stenosis without concomitant discectomy. Canal stenosis without discectomy: 10 year 83.7 ± 9.3%; 14 year 83.7 ± 9.3%. Discectomy with or without undercutting: 10 year 81.4 ± 9.1%; 14 year 78.1 ± 10.1% no significant difference

revision surgery adjacent to the index fusion. This can be compared with our overall revision rate of 17.2% at 10 years, a percentage that includes both adjacent level and index level revision operations.

The degree of success of adjuvant first-generation Wallis device use in terms of reoperation rate and implant survival did not depend on the number of segments treated (Fig. 5). This contrasts with the lumbar fusion failure rate, which is reported to increase with the number of fused segments [7, 15]. The observed absence of difference between the actuarial survivorship of the single-level implants and the multiple-level implants also supports the safety and efficacy of each segment of these multi-level dynamic constructs. If the system had inherent flaws, one would expect poorer outcome in a series of double-level implants, not to mention in patients with three or four instrumented levels. Moreover, because the patients operated at two, three or four levels arguably had more advanced degenerative lesions than those operated at one level, the lack of difference in outcome of the two groups is particularly noteworthy.

When one of the devices had to be removed, the revision procedure was straightforward with no implant-related complications, comparable to reoperations after isolated discectomy, for which there is no implant to remove. Among the 72 long-term follow-up patients who initially underwent discectomy with or without bony decompression (actuarial survival curve shown in Fig. 6), 19 (26.4%) with a follow-up of 12.0 ± 2.4 years were reoperated, the implant being removed in 16 and left in place in three. This was similar to the value reported from the prospective Maine Lumbar Spine Study [2], in which, among 217 patients who were operated for sciatica by discectomy without fusion, 51 (23.5%) underwent unspecified lumbar reoperations within 10 years. The latter group of patients may have had less advanced degenerative lumbar changes than our 72 contacted patients who underwent discectomy, given that 27 (37.5%) were operated for a recurrent disc and 30 others (41.7%) for canal stenosis decompensated by a herniated disc.

Among the 142 patients contacted in the present series, 57 received the implant at the end of an undercutting procedure for canal stenosis alone. There is evidence suggesting that segments with early degenerative changes and only partially diminished disc height contribute more to lumbar flexion and extension than the healthier segments. This ‘‘hinge effect’’ is thought to constitute a dynamic factor that can worsen the symptoms of static canal stenosis [20]. Fusion eliminates the hinge effect in treated segments and the interspinous stabilization device probably reduces it. One of the only long-term magnetic resonance images recovered from the first-generation implant series may be of interest. Because of a current neck problem, one patient was referred to us 15 years after a canal enlargement at L3–L4 and L4–L5 stabilized by a double-level device. The follow-up MRI shows the absence of stenosis above the implants [16]. Although MRI generally shows no recurrence of stenosis in lumbar canal segments enlarged and stabilized by fusion, narrowing of one or more levels proximal to the treated segments may develop. In fact, whether fusion contributes to stenosis at the level adjacent to fused segments remains controversial. With follow-up ranging from 21 to 52 years, Lehmann et al. [11] reported 30% of patients developed spinal stenosis at the level above posterior lumbar fusion). In contrast, Fraser's group observed spinal stenosis above a solid anterior lumbar fusion in only two of 81 patients (2.5%) 11–14 years after the procedure [14]. Nonetheless, inhibition of the ‘‘hinge effect’’ and possible prevention of degeneration at adjacent levels by adding single- or multiple-level devices after decompression of canal stenosis probably merit further study. Eleven (19.0%) of the 58 patients operated for canal stenosis alone were reoperated. In a long-term study of patients operated for canal stenosis, Atlas et al. [1] proposed considering an operation to be successful if no reoperation has been performed before 8 years. Applying this criteria to our patients, the number of ‘‘failures’’ drops to eight (13.8%). In the patient subgroup operated for canal stenosis, 24 (42%) had the implants for more than 14 years at follow-up. These values can be compared with the Maine Lumbar Spine Study [1], which reported that in 63 patients treated surgically (decompression laminectomy, rarely fusion, and none with internal fixation devices) for lumbar canal stenosis, 15 (23.8%) were reoperated within 8–10 years.

In 26 patients, the implant was removed at some point. The removal of a Wallis implant is straightforward. It is important to note that, during these removal procedures, there were no reported complications. This should be compared with the complication rates of revision procedures after failed arthrodeses or disc replacements, reoperations which can be demanding and may expose patients to greater risks than does revision of a Wallis device [5, 10].

Although the clinical and radiological follow-up of these patients is beyond the scope of the present report, we have included typical images from a few patients with various indications for the procedure (Figs. 7, 8, 9, 10). These figures illustrate how disc height observed immediately after the procedure is generally preserved at long-term follow-up as is a limited degree of motion in the treated segment.

Conclusions

Despite limitations related to the high attrition rate, this first long-term analysis of an interspinous dynamic lumbar stabilization system provides promising information. The

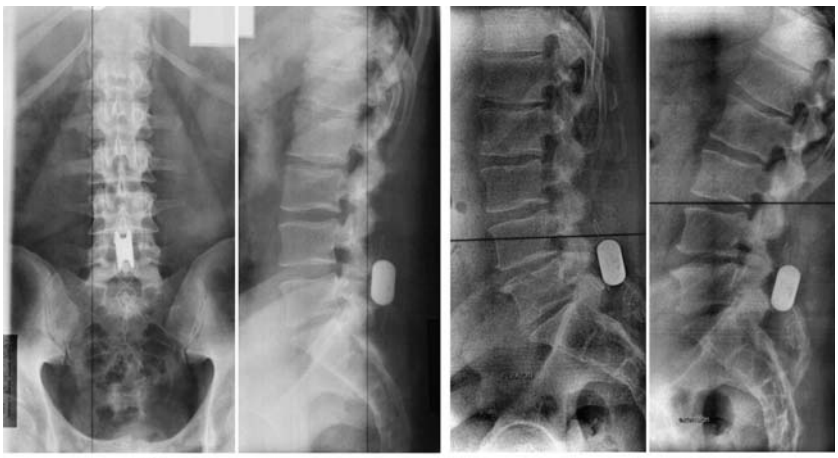

Fig. 7 Patient 35, when he was 29 years old, this male banker (1 m 80, 95 kg) received a first-generation Wallis implant at L4–5 and L5–S1 for stabilization after undercutting at those levels for canal stenosis. At 15-year follow-up, the patient has no low-back or leg pain and no walking limitation. His Oswestry disability score (ODI) is 4/100. The treated discs appear relatively well preserved on the follow-up films

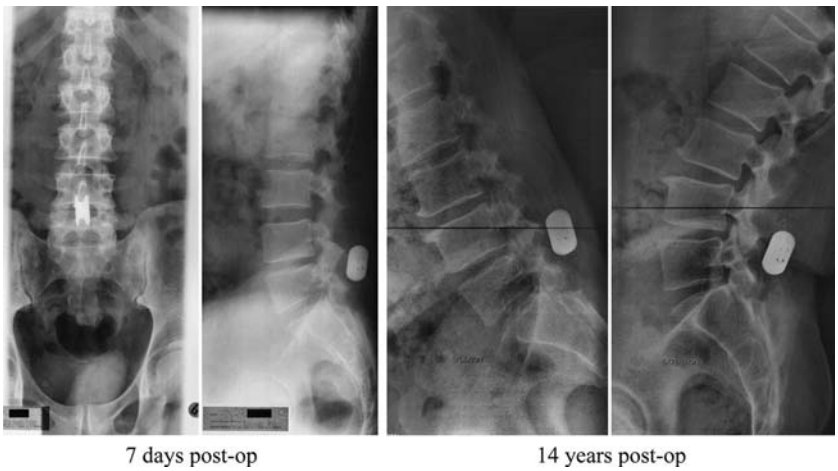

Fig. 8 Patient 90, at the age of 42, this male office worker received a stabilization device during the course of an operation for recurrent disc at L4–5. At 14-year follow-up, the patient has no low back pain and slight leg pain with an ODI score of 10/100. The bending films show that disc height and mobility are well preserved

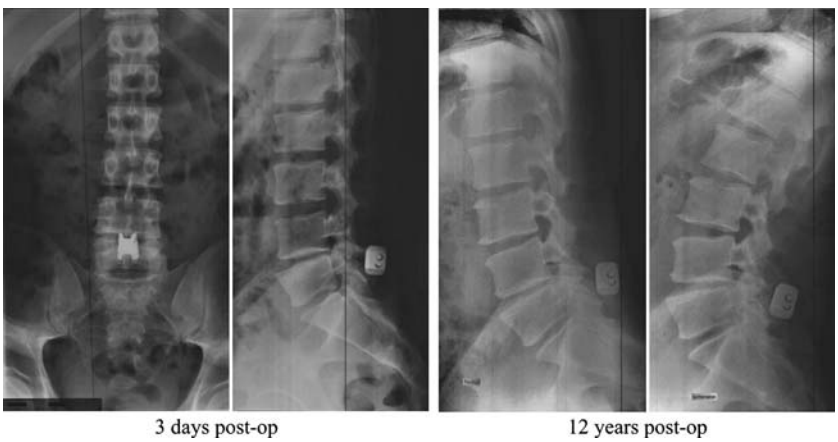

Fig. 9 Patient 116, this 32-year old man was operated for chronic permanent low back pain attributed to instability at L4–5 in 1991. There was no disc or bone decompression associated with the first-generation Wallis procedure. He was immediately relieved by the implant. Today he works as a mountain photographer. He has no low back pain and his ODI score is excellent (4/100). The initially intermediated disc height has been preserved and the mobility at L4–5 persists

primary relevance of this study was that it demonstrated the long-term safety of the system. The aim of the study was not to demonstrate superiority of the device over fusion. The goal was to delay a relatively invasive fusion procedure for as long as possible (even definitively) with a simple superficial device that preserved the segmental anatomy. In achieving this goal in around 80% of the patients for 14 years, the first-generation Wallis implants demonstrated efficacy in delaying fusion. When revision was necessary, there were no implant-related complications and the surgical procedure was quite straightforward. In terms of reoperation rates, the long-term outcomes of the first-generation

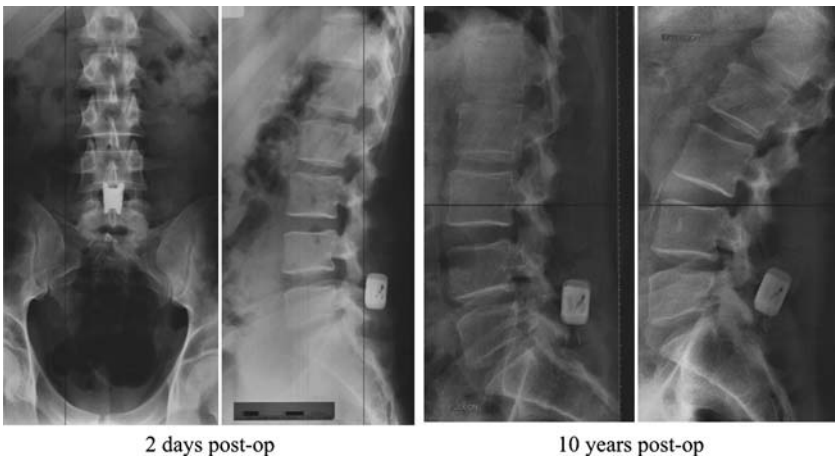

Fig. 10 Patient 187, this 25-year-old unqualified laborer (1 m78, 78 kg) was operated for a recurrent L4–5 disc and had undercutting at that level for a narrow canal. L4–5 was stabilized with a first-generation implant. At 10-year follow-up, he has occasional bouts of low back pain, but no leg pain. His ODI score is 14/100. The images suggest good preservation of the disc, despite the 10 years of heavy work

Wallis implants indicate that it may be a valuable addition to our therapeutic armamentarium for degenerative lumbar segments, notably after decompressive procedures for certain cases of herniated disc occurring in segments with advanced changes and instability, and after decompression for canal stenosis. With the endpoint 'any subsequent lumbar operation', the actuarial survivorship analysis compares favorably with that of revision operations adjacent to lumbar fusion procedures recently reported in the literature. This might reflect long-term protective action against adjacent-level degeneration by motion preservation. More importantly, this was not a fusion procedure. Contrary to fusion, the vertebrae, discs, facet joints and ligaments except for the interspinous ligament were left intact and functional at surgery so that all therapeutic options remained open. This is a safe device that can without great risk be used when a decompressive procedure is being done, possibly reducing the incidence of a further operation.

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